NHS Resolution

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

22 January 2026

REF: 26765

APPEAL AGAINST LANCASHIRE AND SOUTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY KIM PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 12 COMMERCIAL STREET, BRIERFIELD, NELSON, BB9 5HH UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

PSCE, on behalf of Lancashire and South Cumbria ICB
Rushport Advisory, on behalf of Kim Pharma Ltd
Brierfield Late Pharmacy

NHS Resolution

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

REF: 26765

APPEAL AGAINST LANCASHIRE AND SOUTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY KIM PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 12 COMMERCIAL STREET, BRIERFIELD, NELSON, BB9 5HH UNDER REGULATION 25

1 The Application

By application dated 10 June 2025, Kim Pharma Ltd ("the Applicant") applied to Lancashire and South Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 12 Commercial Street, Brierfield, Nelson, BB9 5HH under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant stated:

1.2 "Drug Tariff part IX*

1.3 *EXCEPT items that require measuring or fitting."

1.4 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:

1.5 "Not applicable as no other pharmacy in same or adjacent premises."

1.6 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.7 "Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

Further Information in Relation to Provision of Essential Services in Accordance With the Regulatory Requirements for Distance Selling Pharmacies

1.8 Please explain below how the pharmacy procedures used within the premises will secure:

(a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

1.9 "SEE ATTACHED INFORMATION"

1.10 [The Applicant provided a copy of its SOPs]

2 **Applicant's '14 day comments' to the Commissioner**

2.1 "Thank you for your letter of 17 August 2025. I act for Kim Pharma Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

2.2 Interested parties ask that the ICB applies the correct legal test when determining the application and my client has provided their SOPs to show that the test will be met in full.

2.3 In response to the comments from Read and Simonstone t/a Briarfield Late Night Pharmacy we reply as follows.

2.4 Brierfield Late Night Pharmacy lists 42 points of objection to my client's application. As the Committee will note, these points are comments about the operation of other DSPs, general points objecting to the existence of DSPs, planning points, personal comments about my client and points that the GPhC would consider as part of its review and registration of any new pharmacy premises.

2.5 None of the objections are relevant to the legal test that the Committee will apply and we therefore do not reply to them.

2.6 **LPC Comments**

2.7 The LPC lists a number of points which appear to be general commentary on DSPs and the LPC's dislike of those pharmacies, which is of course of no relevance to the legal test.

2.8 Comments about other existing DSPs and breaches of Regulations should be raised with the ICB specifically in relation to the contractor that is alleged to be in breach of their Terms of Service and are not relevant to my client's application.

2.9 Dealing with some of the bullet points listed in the LPC letter we reply as follows.

2.9.1 The LPC should be aware that the superintendent pharmacist is not annotated on the GPhC until after they submit a nomination of superintendent form which is sent at the same time as the premises registration form. This will occur after NHS approval.

2.9.2 The location of other pharmacies is irrelevant.

2.9.3 Almost all pharmacy contractors purchase 3rd party SOPs including the pharmacies that the LPC represents. It is not clear from the LPC comment if they are criticising all pharmacies that they represent, or only my client.

2.9.4 Comments on opening hours are irrelevant to the legal test.

2.9.5 Premises security is a matter that the GPhC assesses. The GPhC will not register premises if they are not secure and the NHS will not include the pharmacy on the pharmaceutical list without the GPhC premises registration being approved.

2.9.6 Re NMS – the premises and contractor will not be accredited until after the pharmacy opens and the LPC should really be aware of this. In no way does this undermine my client's ability to provide services safely and effectively and it is unfortunate for the LPC to make such a claim.

2.9.7 As already noted above, criticism of other pharmacies is of no relevance to my client's application.

2.10 **Regulatory Changes and NMS**

2.11 As a result of the changes made to the Regulations on 23 June 2025, the Committee will no longer consider only the safe and effective provision of essential services and will instead consider the provision all NHS pharmaceutical services provided to patients.

2.12 My client has updated their SOPs to reflect the new legal test and the SOP for NMS has been added and is attached to this reply for the consideration of the Committee.

2.13 The information already provided demonstrates how the legal test will be met in full and the application should therefore be approved.

2.14 We look forward to hearing from you in due course."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 21 October 2025 states:

3.1 "Lancashire and South Cumbria ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

3.2 You have a right of appeal to the Secretary of State against Lancashire and South Cumbria ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

3.3 Primary Care Appeals
NHS Resolution

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU”

Determination – Pharmaceutical Services Group

3.4 “The application is for distance-selling with no patient access to essential services face-to-face and gives assurances that:

3.4.1 the premises listed in the application are not on the same site or in the same building as a GP practice

3.4.2 the applicant is not seeking to restrict the provision of essential services in any way

3.4.3 there will be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services

3.4.4 the safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else’s behalf, and the applicant or the applicant’s staff

3.5 Using the NHS website, there are 4 other pharmacy contractors within 1 mile of the proposed premises. There are 7 GP practices currently listed within 1 mile of the proposed premises.

3.6 Using googlemaps, the proposed premises are currently a residential building on a terraced road. Access to the proposed premises is at street level.

3.7 It is not on the same site or in the same building as a provider of primary medical services with a patient list.

3.8 In representations, concerns raised included about the layout and security of the premises, cold chain and waste procedures and face-to-face interactions.

3.9 The Applicant has provided evidence to maintain that granting of the application will support the provision of services and that they will be provided and accessible to patients. The Applicant supported this by providing the information regarding how it intends to carry on the provision of services.

3.10 All representations were considered, including from the Applicant.

3.11 Within the 45-days consultation period, representations were received from:

3.11.1 Brierfield Late Night Pharmacy

3.11.2 Community Pharmacy Lancashire and South Cumbria (CPLSC)

3.12 Outline of Representations

3.13 **Brierfield Pharmacy** provides an extensive portfolio to support its opinion that this application should be refused covering issues, including:

3.13.1 Local provision only

3.13.2 Premises readiness

3.13.3 Training

3.13.4 Hours of operation

3.13.5 PNA

3.13.6 SOPs, cold chain, etc.

3.14 **CPLSC** opposes the application, questioning whether the services will be carried out in a professional way (e.g., dispensary layout and access/security) according to the 'generic' set of procedures submitted and whether there is a benefit of another pharmacy in the area, particularly when not opening on weekends.

3.15 **CPLSC** notes that:

3.15.1 The floorplan should be considered with regards to security.

3.15.2 The applicant has failed to demonstrate compliance with regulations, especially uninterrupted service provision along with safe and effective provision.

3.15.3 No supporting documentation or SOPs to support this. The application does not sufficiently explain how essential services will be delivered in a manner that meets the requirements of Regulation 25(2)(b), particularly the obligation to avoid face-to-face contact at the pharmacy premises.

3.15.4 Given these deficiencies, CPLSC believes the application does not meet the regulatory standards and should therefore be refused.

3.15.5 Provides a summary of and a report from 2023 regarding DSPs and contractual obligations.

3.16 In summary, **CPLSC** submits that the application lacks sufficient detail on how essential services will be delivered uninterruptedly and safely without face-to-face contact, as required under Regulation 25(2)(b).

3.17 There were no responses to the representations from interested parties. In response to the representations from interested parties, the **Applicant** refutes the comments and asserts that it has provided evidence that shows that the legal tests will be met in full. Additionally, SOPs for the future provision of NMS have been provided.

3.18 **ICB Professional Advisor** – following assessment of the Application, the Professional Advisor has noted:

3.18.1 The ICB does not approve or authorise SOPs for any contractor.

3.18.2 It is observed that the SOPs provided are 'generic'.

3.18.3 No specific premises assurances. No way to assess access as described. Previous applications have indicated similar and upon presentation of a floor plan did not meet requirements.

3.18.4 No assurances for cold chain. Applicant assures having several to hand, but unable to specify one in the document.

3.18.5 SOPs appear to cover waste and DSP-ready interactions

3.18.6 In any contractual or controlled drugs visit undertaken by the ICB, we will consider the observed pharmaceutical practices in line with the prevailing or most current SOPs available.

3.18.7 Overall, advise that the specific assertions are not adequate to assure the Group fully.

3.19 Regulation 31

3.20 The Group noted that Regulation 31 does not apply, as the applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide.

3.21 The Group therefore considered the application under Regulation 25, set out below, and took into account all information provided by the applicant and interested parties. The Group determined the following:

3.22 *"Distance selling premises applications*

25.— (1) Section 129(2A) of the 2006 Act(c) (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.

3.23 The application has been checked, and all relevant information is provided and meets the criteria of the Regulations, including Fitness to Practise. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

3.24 *(2) The NHSCB must refuse an application to which paragraph (1) applies—*

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

3.25 The premises listed in the application are not on the same site or in the same building as a provider of primary medical services with a patient list. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

3.26 *(b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*

(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

3.27 The applicant has stated the services and hours that will be provided at the new site, supported by procedures to maintain uninterrupted provision of services. However, from the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations, particularly in regards to face-to-face provision.

3.28 *(ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

3.29 Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

3.30 **Decision – REFUSED.**

3.31 Appeal Rights to the Applicant."

4 The Appeal

In a letter dated 21 October 2025, the Applicant, through its representative Rushport Advisory LLP, appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for Kim Pharma Limited and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.

4.2 As the Committee will note, the Commissioner's reason for refusing the application is stated at page 4 as follows.

4.2.1 *Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.*

4.3 It is not entirely clear what the Commissioner means. Security of premises is a matter for the GPhC. The GPhC must inspect and approve any pharmacy

premises and an Applicant must provide their GPhC premises registration number when they submit their Notice of Commencement form to the Commissioner.

4.4 In respect of “cold chain” my client’s SOPs describe at length how this would be maintained for all deliveries.

4.5 Since my client submitted their application they have prepared a floor plan and for the sake of completeness it is attached along with this appeal.

4.6 In addition, my client has instructed me to submit the attached SOPs that have been approved by my client for use at the proposed pharmacy and we trust that these provide the Committee with sufficient detail to allow the appeal. These SOPs include a number of small changes compared to the SOPs that my client submitted with their original application and the previous version of the SOPs should now be disregarded.

4.7 We look forward to hearing from you in due course.”

5 Summary of Representations

After reviewing the paperwork to the Commissioner, it was noted that the comments made by the Applicant in response to the representations on the application [see 2.1 – 2.14 above] had not been circulated or seen by parties. NHS Resolution therefore applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed parties the opportunity to make comments on these.

Representations were also sought from the Applicant on the amendments to Regulation 25 as the Commissioner considered the application against the previous regulatory test.

This is a summary of representations received on the appeal.

5.1 Rushport Advisory LLP, on behalf of the Applicant

5.1.1 “We have no further comments as the appeal addresses the new legal test.”

5.2 Brierfield Late Night Pharmacy

5.2.1 “Representations in Response to Applicant’s Appeal – SHA/26765

5.2.2 Submitted pursuant to NHS Resolution letter dated 12 November 2025

5.2.3 These representations are submitted in accordance with Schedule 3, Part 3, paragraph 7 of the Regulations, pursuant to the invitation issued by NHS Resolution.

5.2.4 FURTHER EVIDENCE SUBMISSION

5.2.5 Further Evidence Submission – DSP Appeal. This Evidence is further to all the points already raised in my previous objection.

5.2.6 This further evidence is submitted to expose, in the clearest and strongest terms, the fundamental failures in the Applicant's appeal and the deeply flawed process that continues to enable Rushport's generic, copy and paste DSP applications to pass on paper while being completely impossible to deliver in reality.

5.2.7 NHS Resolution repeatedly accepts Rushport's template SOP bundles—identical documents submitted across countless applications—with no scrutiny of whether any of the systems described actually exist. These SOPs are not evidence. They are theoretical scripts designed solely to tick regulatory boxes, and NHS Resolution has become far too willing to accept them without verifying a single operational detail. The result is predictable: unsafe, unlawful, speculative DSP approvals that collapse immediately after being granted.

5.2.8 This case exposes the problem perfectly.

5.2.9 The Applicant is a 19-year-old with no pharmacy background, no superintendent pharmacist, no governance systems, no training, no staff, no planning, and no operational capacity. His premises—a fully occupied residential dwelling—remain untouched, unconverted, unlawful for pharmacy use, and structurally incapable of ever meeting GPhC or DSP contractual requirements. Nothing in the Applicant's appeal addresses these facts because they cannot be addressed.

5.2.10 Worse still, this is not his first failed attempt. He has already secured one DSP approval (almost certainly using the same Rushport templates) at 37A Railway Street, and did absolutely nothing with it. No works. No planning. No opening. No activity. Nothing. It was a speculative grab for an NHS contract—then abandoned. This application is exactly the same. He has also had 47 Every Street, Nelson, BB9 7LU as a company address and no planning applications have been submitted for all 3 premises (see attached). Also see photos and video attached for 12 Commercial St BB9 5HH on 10/12/25. The property in [sic] untouched and not what Rushport is implying in their SOPs.

5.2.1 This is not national service provision.

5.2.2 This is not a lawful DSP model.

5.2.3 This is a disguised attempt to siphon local prescriptions from an established pharmacy by exploiting a loophole NHS Resolution continues to tolerate.

5.2.4 Meanwhile, NHS England's persistent failure to regulate DSP operators after approval forces compliant contractors like myself to police the sector. Every three months we must pull PMR reports to identify which DSPs—approved on the basis of Rushport paperwork—are diverting nominations without ever providing lawful or compliant services. This burden exists solely because NHS Resolution continues granting DSPs

"on paper" without inspecting premises, verifying evidence, or applying the same basic checks the GPhC performs before registration.

5.2.5 These facts must be made absolutely clear:

5.2.5.1 Rushport's submissions are generic templates, not evidence.

5.2.5.2 NHS Resolution is repeatedly accepting these templates without verifying a single claim.

5.2.5.3 The Applicant has no lawful, safe, or functional premises.

5.2.5.4 The Applicant has no capacity, no governance, and no credibility.

5.2.5.5 The application is a deliberate attempt to target local prescriptions while pretending to be a DSP.

5.2.6 There is nothing borderline about this case. It is not capable of being salvaged, corrected, deferred, or conditioned. It is structurally incapable of meeting Regulation 25 or Schedule 4 because the entire model is fictional.

5.2.7 This appeal should not only be refused—it should prompt urgent scrutiny of why NHS Resolution continues approving identical Rushport designed DSP applications without inspecting the premises, verifying operational readiness, or requiring any real evidence.

5.2.8 This application is unsafe, unlawful, speculative, paper only, and fundamentally incompatible with the DSP contract. It must be rejected in full.

5.2.9 Full Legal Rebuttal & Evidence Bundle Prepared for NHS Resolution

5.2.10 1. Executive Summary

5.2.11 This Executive Summary sets out, in the clearest and strongest possible terms, why the application submitted by Kim Pharma Ltd for a Distance Selling Pharmacy (DSP) at 12 Commercial Street must be refused. The Applicant's 14-day comments, drafted by Rushport Advisory LLP, contain material misinterpretations of law, substantial omissions, and a complete failure to address any of the deficiencies raised by the ICB, LPC, CPL, or Brierfield Late Night Pharmacy.

5.2.12 The statutory test under Regulation 25(2)(b) is strict, mandatory, and requires the Commissioner to be satisfied — at the time of application — that the pharmacy can operate safely, effectively, and without any facetoface provision. The Applicant fails to satisfy any limb of this test.

5.2.13 The premises are legally incapable of pharmacy use, the Applicant lacks experience and operational capability, and the application constitutes a textbook example of DSP misuse. Approval would be unsafe, unlawful, and contrary to multiple NHS Resolution precedents.

5.2.14 This submission provides a complete and devastating rebuttal of the Applicant's claims and demonstrates that the refusal must be upheld without qualification.

5.2.15 2. Background & Context

5.2.16 This section sets out the factual and procedural background to this application, while making explicit from the outset the fundamental structural defects and misconduct indicators embedded throughout the Applicant's behaviour, submissions, and choice of premises.

5.2.17 The Applicant, Kim Pharma Ltd, submitted a Distance Selling Pharmacy (DSP) application for 12 Commercial Street, Brierfield — a residential property still occupied by tenants, not owned by the applicant, lacking planning permission, lacking lawful change-of-use, and wholly incapable of meeting even the minimum GPhC requirements for pharmacy registration.

5.2.1 See Photos attached taken on 12/12/2025 of the premises 12 Commercial St UNTOUCHED and planning portal for 12 Commercial St and 74 railway St Nelson (No change planning applications have been made for 12 Commercial St and non were made for the applicants previous DSP application either. 37a Railway St either).

5.2.2 From the day the application was filed, the Applicant has provided no physical evidence except SOPs:

5.2.2.1 no evidence of premises readiness,

5.2.2.2 no lawful authority to use the building,

5.2.2.3 no evidence of vacant possession,

5.2.2.4 no security measures,

5.2.2.5 no cold-chain capability,

5.2.2.6 no governance framework,

5.2.2.7 no workforce,

5.2.2.8 no national logistics,

5.2.2.9 no clinical infrastructure,

5.2.2.10 no adapted SOPs,

5.2.2.11 Floor plans -Are they an estimate as tenants are still in there?

5.2.2.12 and no assurance against face-to-face activities.

5.2.3 In short: the Applicant applied for a DSP that physically, legally and operationally cannot exist.

5.2.4 The ICB, LPC, CPL, and Brierfield Late Night Pharmacy all identified the same fatal flaws. The Applicant's 14-day comments — drafted by Rushport Advisory LLP — failed to address even a single one of these issues. Instead, the comments were composed of dismissals, misstatements of law, and a strategy aimed at minimising defects rather than remedying them.

5.2.5 Furthermore, the Applicant's choice of premises and operational behaviour fits the classic profile of DSP misuse identified in DHSC's 2024 DSP Pause: a speculative operator attempting to open a disguised local competitor, with zero evidence of national service capacity.

5.2.6 The Applicant's track record reinforces this pattern. They already have an approved DSP at 37A Railway Street — and have failed to open it. This is a critical indicator of inexperience, non-compliance, and speculative intent.

5.2.7 Taken together, the factual context shows an Applicant who:

5.2.7.1 has no lawful, safe, or compliant premises,

5.2.7.2 has no operational or clinical infrastructure,

5.2.7.3 has no history of service delivery,

5.2.7.4 has already failed to operationalise an NHS contract,

5.2.7.5 and now attempts to rely on legally defective arguments presented by Rushport.

5.2.8 This is the background in which this rebuttal is presented: an application that was fundamentally unfit from inception and remains unfit now.

5.2.9 3. Statutory Framework (Regulation 25, Schedule 4, DSP Law)

5.2.10 This section sets out the full statutory and regulatory framework governing Distance Selling Pharmacies (DSPs), and demonstrates unequivocally that the Applicant fails every aspect of it. This is not a borderline failure— it is a complete collapse against the mandatory legal test. The Applicant's 14-day comments show a profound misunderstanding of the law, and Rushport's submissions misstate, minimise, or ignore binding statutory requirements.

5.2.11 A. REGULATION 25(2)(b) — THE MANDATORY THRESHOLD TEST

5.2.12 Regulation 25(2)(b) requires the Commissioner to be satisfied, at the time of determining the application, that:

5.2.12.1 Essential services will be provided safely and effectively.

5.2.12.2 Services will be provided without interruption.

5.2.12.3 Services will be provided without any facetoface interaction.

5.2.12.4 The contractor has the procedures, governance, premises, and systems necessary for national remote service delivery.

5.2.13 This is a PRESENT CAPABILITY TEST. Evidence is required NOW. Not later. Not post approval. Not “once GPhC visits.”

5.2.14 The ICB explicitly stated the Applicant provided NO such evidence. Therefore, the legal test fails immediately.

5.2.15 B. APPLICANT FAILS EVERY LIMB OF REGULATION 25(2)(b)

5.2.16 The Applicant fails all four mandatory limbs:

5.2.16.1 No evidence of safe provision (no security, no floor plan, no cold chain).

5.2.16.2 No evidence of uninterrupted provision (no staff, no logistics, no systems).

5.2.16.3 No evidence of nonfacetoface provision (residential premises, no layout, no operational segregation).

5.2.16.4 No evidence of procedures at all (generic SOPs, unadapted, theoretical, and incomplete).

5.2.17 C. SCHEDULE 4 — THE DSP CONTRACTUAL OBLIGATIONS

5.2.18 Schedule 4 requires every DSP to:

5.2.18.1 Provide services to ALL of England.

5.2.18.2 NOT target local patients.

5.2.18.3 Maintain national delivery infrastructure.

5.2.18.4 Maintain functional remote consultation facilities.

5.2.18.5 Maintain safe, secure, compliant premises.

5.2.19 The Applicant breaches every one:

5.2.19.1 They have no national infrastructure.

5.2.19.2 They are opening 270 yards from an existing contractor (local targeting).

5.2.19.3 They have no delivery systems.

5.2.19.4 They have no consultation facilities.

5.2.19.5 Their premises cannot be made safe, secure, or compliant.

5.2.20 D. GPhC ‘FITNESS OF PREMISES’ REQUIREMENTS

5.2.21 A premises cannot be registered unless it:

5.2.21.1 has lawful planning consent,

5.2.21.2 has disabled access,

5.2.21.3 has a clinical environment,

5.2.21.4 has secure storage,

5.2.21.5 has fire-safety compliance,

5.2.21.6 has a safe layout and workflow.

5.2.22 The Applicant:

5.2.22.1 has no planning permission,

5.2.22.2 has tenants in situ,

5.2.22.3 has no disabled access,

5.2.22.4 has no clinical room,

5.2.22.5 has no lawful or safe workflow.

5.2.22.6 These failures alone prevent the premises from EVER being registered.

5.2.23 E. NHS RESOLUTION PRECEDENT — EVERY RELEVANT CASE IS AGAINST THE APPLICANT

5.2.24 NHS Resolution has refused DSP applications for far less severe failures. Precedent shows rejection where:

5.2.24.1 generic SOPs were provided,

5.2.24.2 premises readiness was unclear,

5.2.24.3 cold chain was not evidenced,

5.2.24.4 governance structures were hypothetical,

5.2.24.5 security arrangements were insufficient.

5.2.25 The Applicant’s failures are vastly more severe and numerous than in any of these cases.

5.2.26 F. RUSHPORT’S MISSTATEMENTS OF LAW

5.2.27 Rushport repeatedly state:

5.2.27.1“Premises readiness is irrelevant.”

5.2.27.2“Security is a GPhC matter.”

5.2.27.3“Planning permission is irrelevant.”

5.2.27.4“Location is irrelevant.”

5.2.27.5“SOPs are adequate evidence.”

5.2.27.6“GPhC will check everything later.”

5.2.28 Every one of these statements is legally wrong, contradicted by:

5.2.28.1Regulation 25,

5.2.28.2Schedule 4,

5.2.28.3GPhC premises guidance,

5.2.28.4NHS Resolution precedent,

5.2.28.5ICB refusal wording.

5.2.29 This is not interpretation. This is misrepresentation.

5.2.30 G. CONCLUSION OF STATUTORY ANALYSIS

5.2.31 The Applicant does not meet, and cannot meet, the statutory framework governing DSPs. Their premises are unlawful. Their systems do not exist. Their governance is theoretical. Their evidence is absent. Their submissions mislead the legal test. Their DSP model is non-functional.

5.2.32 Regulation 25(2)(b) is failed in full. Schedule 4 is breached in full. GPhC premises standards cannot be met. NHS Resolution precedent demands refusal.

5.2.33 This statutory framework section alone is fatal to the Applicant’s case.

5.2.34 4. Summary of Applicant’s 14-Day Comments

5.2.35 This section provides a full breakdown of the Applicant’s 14-day comments as drafted by Rushport Advisory LLP. Every point they submitted is summarised below — immediately followed by a clear statement of why the point is factually wrong, legally incorrect, misleading, incomplete, or wholly incompetent.

5.2.36 A. CLAIM: “None of the objections raised by the Respondent, LPC or ICB are relevant to the legal test.”

5.2.37 FACT: This is categorically false. Every objection raised relates directly to Regulation 25(2)(b) — including premises readiness, governance,

security, cold chain, planning, safety, and facetoface risks. Rushport's assertion shows a fundamental misinterpretation of the law.

5.2.38 B. CLAIM: "Premises readiness is not required at the application stage."

5.2.39 FACT: This is a blatant misstatement of law. Regulation 25(2)(b) is a PRESENT CAPABILITY TEST.

5.2.40 The Commissioner must be satisfied NOW — not after GPhC inspection. Premises readiness is essential.

5.2.41 C. CLAIM: "Security is solely a GPhC matter and should not be considered by the ICB or NHS Resolution."

5.2.42 FACT: Wrong. Safety is explicitly part of essential service provision under Regulation 25(2)(b). Lack of shutters, no CCTV, no secure storage, and tenants inside the premises make the DSP impossible to operate safely.

5.2.43 D. CLAIM: "Planning permission is irrelevant to the application."

5.2.44 FACT: False. A residential premises with tenants cannot be registered with the GPhC. Without lawful planning use, the premises cannot legally be a pharmacy — making the application unapprovable.

5.2.45 E. CLAIM: "Location of other pharmacies is irrelevant under DSP rules."

5.2.46 FACT: Misleading. DSPs MUST provide services nationally and MUST NOT target local populations. Opening 270 yards from an existing pharmacy is clear evidence of local targeting — a direct breach of Schedule 4.

5.2.47 F. CLAIM: "SOPs submitted by the Applicant demonstrate operational capability."

5.2.48 FACT: Incorrect. The SOPs are generic templates, unadapted, unreferenced, and identical to those used in their previous DSP application (which they failed to open). SOPs are theoretical and cannot replace actual evidence.

5.2.49 G. CLAIM: "Face to face contact is prohibited and therefore will not occur."

5.2.50 FACT: Unsupported and unproven. The Applicant provided no mechanisms, layout, staffing flows, or procedures to ensure no face to face activity. A residential, tenant occupied property cannot operate without contact.

5.2.51 H. CLAIM: "Cold chain is irrelevant because there are no plans to store such medicines initially."

5.2.52 FACT: Incorrect and unsafe. All DSPs must maintain full essential service capability, including cold-chain handling. The Applicant

provided no refrigeration, no monitoring, no contingency plan, and no secure area.

5.2.53 I. CLAIM: “The Applicant intends to serve the whole of England.”

5.2.54 FACT: Unsupported. No national delivery contracts, no systems, no logistics, no staff. This is an unfounded assertion with no operational evidence.

5.2.55 J. CLAIM: “NMS provision is irrelevant to the application.”

5.2.56 FACT: Wrong. NMS is an essential service [sic]. DSPs must provide it remotely using compliant facilities. The Applicant has no consultation room, no remote systems, and no governance records.

5.2.57 K. CLAIM: “ICB’s concerns are misplaced and should be disregarded.”

5.2.58 FACT: Absurd. The ICB is the statutory decision-maker and identified multiple failures under Regulation 25. Rushport provides no evidence to contradict a single finding.

5.2.59 L. CLAIM: “Respondent’s objections should carry little weight.”

5.2.60 FACT: Incorrect. Respondent supplied photographic evidence, legal evidence, factual evidence, and statutory failures that remain unanswered.

5.2.61 M. CLAIM: “The Applicant’s previous DSP inactivity is irrelevant.”

5.2.62 FACT: Misleading. Failure to operate an already-approved DSP is a critical indicator of incompetence, non-compliance, and speculative application behaviour.

5.2.63 OVERALL CONCLUSION OF SECTION 4: The Applicant’s 14-day submission is built on misstatements of law, unsupported assertions, and total avoidance of every core regulatory requirement. Each point collapses under scrutiny.

5.2.64 5. Full Rebuttal (Point-by-Point)

5.2.65 This section provides the complete, exhaustive, and ultra-aggressive rebuttal of every argument put forward by the Applicant and Rushport. It combines deep statutory analysis, operational evidence, governance failings, premises defects, planning issues, credibility failures, contractual history, and DSP misuse patterns. It is intentionally structured as a decisive legal demolition, removing all possible grounds for approval.

5.2.66 A. THE APPLICANT HAS NO LAWFUL PREMISES — THE ENTIRE APPLICATION COLLAPSES HERE

5.2.67 The premises are residential.

5.2.68 Tenants are currently in occupation.

5.2.69 No planning permission has ever been applied for.

5.2.70 No lawful change-of-use exists.

5.2.71 No structural adaptations have taken place.

5.2.72 No disabled access, no clinical room, no fire exits. A DSP cannot legally operate from this building. The GPhC cannot register it. Regulation 25(2)(b) cannot be satisfied. This is a fatal, uncurable defect.

5.2.73 B. ZERO EVIDENCE OF PREMISES READINESS

5.2.74 Rushport argues premises readiness is “irrelevant.” This is a misstatement of law. Regulation 25 is a PRESENT TEST. Evidence is required NOW. The Applicant provided:

5.2.74.1 No floor plan

5.2.74.2 No internal photos

5.2.74.3 No workflow

5.2.74.4 No storage plan

5.2.74.5 No secure areas

5.2.74.6 No consultation facilities

5.2.74.7 No medicine segregation systems

5.2.75 The ICB confirmed this as a core reason for refusal.

5.2.76 C. NO SECURITY — NO SAFE SERVICE

5.2.77 DSPs must ensure safe, secure medicine handling. Applicant provided:

5.2.77.1 No shutters

5.2.77.2 No CCTV

5.2.77.3 No alarm

5.2.77.4 No secure controlled drug storage

5.2.77.5 No secure entry In an area with known break-ins, the Applicant’s chosen premises represent an immediate security failure.

5.2.78 D. NO COLD CHAIN — NO ESSENTIAL SERVICES Applicant must provide all essential services. Cold chain is mandatory. They provided:

5.2.78.1 No fridge

5.2.78.2 No temperature logs

5.2.78.3 No monitoring system

5.2.78.4 No contingency plans

5.2.78.5 No evidence of any capacity

5.2.79 This alone requires refusal.

5.2.80 E. GENERIC, COPY-PASTE SOPS — NOT EVIDENCE

5.2.81 Their SOPs are:

5.2.81.1 not adapted,

5.2.81.2 not referenced,

5.2.81.3 not linked to real premises,

5.2.81.4 identical to their previous DSP (never opened),

5.2.81.5 contain contradictions.

5.2.82 NHS Resolution precedents reject DSPs that rely on theoretical SOPs unsupported by real systems.

5.2.83 F. NO STAFF, NO TRAINING, NO GOVERNANCE

5.2.84 Applicant provided ZERO evidence of:

5.2.84.1 Qualified staff

5.2.84.2 Induction plans

5.2.84.3 Training logs

5.2.84.4 Governance sessions

5.2.84.5 Responsible pharmacist arrangements

5.2.85 A DSP cannot legally operate without a governance framework. The Applicant has none.

5.2.86 G. DSP MISUSE — THIS IS A LOCAL TARGETING OPERATION

5.2.87 DSPs must operate nationally. Applicant is locating 270 yards from an existing pharmacy. They have:

5.2.87.1 No national delivery contracts

5.2.87.2No national advertising

5.2.87.3No national systems

5.2.88 This fits the exact DSP misuse pattern identified by DHSC in the 2024 DSP Pause.

5.2.89 H. APPLICANT'S AGE, EXPERIENCE & HISTORY EXPOSE INCOMPETENCE

5.2.90 Applicant is 19. Has never operated a pharmacy. Has never operated a DSP. Has never worked in NHS governance. Has never delivered clinical services. Has never run remote systems. This level of inexperience is incompatible with a national DSP.

5.2.91 I. FAILURE TO OPEN PREVIOUS DSP — CRITICAL EVIDENCE OF NON-COMPLIANCE

5.2.92 Applicant already has an approved DSP (37A Railway Street). They never opened it. This shows:

5.2.92.1inability to plan,

5.2.92.2inability to execute,

5.2.92.3inability to operate safely,

5.2.92.4speculative intent.

5.2.93 This is one of the strongest indicators for refusal.

5.2.94 J. RUSHPORT'S ARGUMENTS ARE FACTUALLY AND LEGALLY WRONG

5.2.95 Rushport claim: "GPhC will sort it later." This is wrong — the law requires capability BEFORE approval.

5.2.96 Rushport claim: "Planning permission irrelevant." Wrong — premises must be legally capable of registration.

5.2.97 Rushport claim: "SOPs are sufficient evidence." Wrong — operational evidence is required.

5.2.98 Rushport claim: "Location irrelevant." Wrong — Schedule 4 prohibits local targeting.

5.2.99 Every key argument Rushport raised is legally incorrect.

5.2.100K. ICB REFUSAL STANDS STRONG

5.2.101ICB identified:

5.2.101.1No premises evidence

5.2.101.2No procedures

5.2.101.3No cold chain

5.2.101.4No security

5.2.101.5No operational systems

5.2.101.6No assurance against face-to-face

5.2.101.7No readiness

5.2.102Rushport failed to rebut ANY of these points.

5.2.103L. RESPONDENT'S, LPC'S & CPL'S POINTS STAND UNCHALLENGED

5.2.104Not one objection raised has been answered. Applicant has not provided evidence to contradict a single finding. The record is entirely one-sided.

5.2.105M. FULL LEGAL CONCLUSION OF REBUTTAL

5.2.106Applicant fails every statutory requirement. Applicant has no lawful premises. Applicant has no systems. Applicant has no workforce. Applicant has no capability. Applicant misinterprets law. Rushport misstates legal tests. The DSP model is misused. The application is speculative. The submission is incompetent. Refusal is mandatory. This section alone is determinative. The application must be rejected.

5.2.107N. APPLICANT'S SOP SUBMISSIONS ARE PURELY PAPER-BASED

5.2.108The Applicant has repeatedly submitted and re-submitted generic SOPs while the physical premises at 12 Commercial Street remain completely untouched and unprepared. No works have commenced, no layout has been implemented, no equipment has been installed and no governance systems have been embedded. All "evidence" of procedures therefore exists only on paper and not in reality. This reinforces that the application is speculative, theoretical and incapable of satisfying Regulation 25(2)(b) in practice.

5.2.1096. Reinforced Objections (You + LPC + CPL + ICB)

5.2.110This section consolidates and weaponises the objections raised by all four key stakeholders: Brierfield Late Night Pharmacy (Respondent), Community Pharmacy Lancashire (LPC), Community Pharmacy Lancashire Clinical Panel (CPL), and the Integrated Care Board (ICB). Every single one of these bodies identified fatal defects. The Applicant and Rushport responded to NONE of them. This establishes total, unrebutted failure.

5.2.111A. ICB OBJECTIONS — THE STATUTORY DECISION-MAKER

5.2.112 The ICB identified:

5.2.112.1 No premises readiness

5.2.112.2 No floor plan

5.2.112.3 No security evidence

5.2.112.4 No cold-chain capacity

5.2.112.5 No governance systems

5.2.112.6 No operational procedures

5.2.112.7 No assurance against face-to-face contact

5.2.112.8 No evidence of safe or effective service provision

5.2.113 Rushport ignored ALL of this. The Applicant remedied NONE of this. These are binding grounds for refusal under Regulation 25(2)(b).

5.2.114 B. LPC OBJECTIONS — PROFESSIONAL OVERSIGHT FAILURES

5.2.115 LPC raised:

5.2.115.1 Generic, unadapted SOPs

5.2.115.2 Lack of staff or training evidence

5.2.115.3 No evidence of remote consultation ability

5.2.115.4 No clinical governance

5.2.115.5 No safe workflow

5.2.115.6 No storage or segregation systems

5.2.115.7 No accessibility or premises safety evidence

5.2.116 These are operational defects that make the DSP unworkable. Applicant provided ZERO evidence in response.

5.2.117 C. CPL OBJECTIONS — CLINICAL AND PATIENT SAFETY FAILURES

5.2.118 CPL highlighted:

5.2.118.1 High-risk unsafe premises

5.2.118.2 Total absence of clinical infrastructure

5.2.118.3 No systems preventing face-to-face contact

5.2.118.4 No capacity to deliver essential services

5.2.118.5 Residential layout incompatible with pharmacy safety

5.2.118.6 No proven capacity for remote clinical provision

5.2.119 Again: no rebuttal, no evidence, no corrective submission.

5.2.120 D. RESPONDENT'S 42-POINT OBJECTION — UNANSWERED IN FULL

5.2.121 Your objection included:

5.2.121.1 Planning failure

5.2.121.2 Tenant occupation

5.2.121.3 Illegal use of premises

5.2.121.4 No ownership

5.2.121.5 No disabled access

5.2.121.6 No lawful GPhC registration path

5.2.121.7 DSP misuse

5.2.121.8 Inexperience

5.2.121.9 Failed previous DSP

5.2.121.10 Security risks

5.2.121.11 Local targeting breach of Schedule 4

5.2.122 The Applicant did not rebut any of these points. Not one word was submitted addressing these facts.

5.2.123 E. TOTALITY OF OBJECTIONS — COMPLETE UNANIMOUS REJECTION

5.2.124 Four independent bodies raised fatal defects. The Applicant answered none. Rushport misrepresented the law instead of providing evidence. There is no balancing argument. There is no counter-evidence. There is no remedial submission. The record is entirely one-sided.

5.2.125 F. LEGAL AND OPERATIONAL CONCLUSION

5.2.126 The Applicant has failed:

5.2.126.1 all statutory tests,

5.2.126.2 all operational requirements,

5.2.126.3all premises requirements,

5.2.126.4all governance requirements.

5.2.127ALL FOUR objecting bodies reached the same conclusion: THE APPLICATION IS UNSAFE, UNLAWFUL, UNREADY, AND UNAPPROVABLE. This combined, unrebutted objection is fatal.

5.2.1287. Premises, Planning, Security & Legal Defects

5.2.129This section demonstrates, beyond any legal doubt, that the premises at 12 Commercial Street are fundamentally, permanently, and fatally incapable of meeting the statutory, regulatory, planning, safety, and operational requirements for a Distance Selling Pharmacy. This is not a borderline case — the premises themselves destroy the application.

5.2.130A. PLANNING LAW — THE PREMISES CANNOT LEGALLY OPERATE AS A PHARMACY

5.2.131The premises are a residential dwelling.

5.2.132No planning application has been submitted.

5.2.133No change-of-use to sui generis or E(e) has been requested.

5.2.134Tenants are still in occupation.

5.2.135The property has no lawful commercial classification.

5.2.136Pharmacy use would be a material change requiring planning approval.

5.2.137A DSP cannot legally operate from this property. GPhC will not register an unlawful premises. NHS Resolution cannot approve a contract that is impossible to register.

5.2.138B. NO VACANT POSSESSION — PHARMACY CANNOT OPEN

5.2.139A pharmacy cannot be operated from a property that:

5.2.139.1still has tenants living inside,

5.2.139.2has not served notice,

5.2.139.3has no evidence of planned vacancy,

5.2.139.4remains in residential use.

5.2.140Vacant possession is mandatory for GPhC inspection. The Applicant cannot obtain it. This is a fatal defect.

5.2.141C. STRUCTURAL UNSUITABILITY OF THE BUILDING

5.2.142The building lacks:

5.2.142.1disabled access,

5.2.142.2step-free entry,

5.2.142.3clinical space,

5.2.142.4consultation room,

5.2.142.5compliant fire exits,

5.2.142.6staff flow zones,

5.2.142.7secure storage areas,

5.2.142.8designated medicine preparation areas,

5.2.142.9any possibility of compliant workflow.

5.2.143Even with investment, the structure cannot meet the physical standards required.

5.2.144D. SECURITY FAILURES — THE PREMISES ARE UNSAFE

5.2.145DSPs must meet high security standards. The Applicant's chosen building has:

5.2.145.1no shutters,

5.2.145.2no reinforced doors,

5.2.145.3no CCTV,

5.2.145.4no alarm,

5.2.145.5no CD cabinet area,

5.2.145.6visible street exposure,

5.2.145.7proximity to known break-ins.

5.2.146A DSP handling POMs cannot legally function without robust, evidenced security controls.

5.2.147E. FIRE SAFETY & HEALTH & SAFETY NON-COMPLIANCE

5.2.148The building has:

5.2.148.1no fire exit signage,

5.2.148.2no extinguishers,

5.2.148.3no staff evacuation routes,

5.2.148.4no separation of clinical and public areas,

5.2.148.5no health & safety documentation,

5.2.148.6no risk assessments,

5.2.148.7no infection control infrastructure.

5.2.149This breaches both GPhC and HSE expectations.

5.2.150F. NO CLINICAL ENVIRONMENT WHATSOEVER

5.2.151The premises have:

5.2.151.1no sink room,

5.2.151.2no clinical-grade flooring,

5.2.151.3no consultation space,

5.2.151.4no controlled airflow,

5.2.151.5no infection control arrangements.

5.2.152A DSP MUST have compliant consultation facilities for NMS and remote clinical care.

5.2.153G. CANNOT BE MADE COMPLIANT — NOT EVEN WITH INVESTMENT

5.2.154Even if:

5.2.154.1planning were applied for,

5.2.154.2tenants were removed,

5.2.154.3renovations were attempted,

5.2.155the building would still fail due to:

5.2.155.1structural limitations,

5.2.155.2layout restrictions,

5.2.155.3corridor width,

5.2.155.4staircase positioning,

5.2.155.5disabled access impossibility,

5.2.155.6lack of space.

5.2.156H. GPhC WILL NOT REGISTER THIS PREMISES

5.2.157GPhC requires:

5.2.157.1lawful use,

5.2.157.2safe access,

5.2.157.3clinical space,

5.2.157.4secure storage,

5.2.157.5safe workflow.

5.2.158None of these can be achieved here. Therefore, registration is impossible.

5.2.159I. LEGAL CONCLUSION OF PREMISES ANALYSIS

5.2.160The premises are unlawful.

5.2.161The premises are unsafe.

5.2.162The premises are structurally incompatible.

5.2.163The premises cannot be registered.

5.2.164The premises cannot be used as a pharmacy.

5.2.165The premises cannot pass planning.

5.2.166The premises cannot pass GPhC inspection.

5.2.167The premises fail Regulation 25(2)(b)(ii).

5.2.168The premises breach Schedule 4.

5.2.169This premises section alone destroys the entire application.

5.2.170J. PRECEDENT: PENDLE COUNCIL REFUSALS OF DWELLING-TO-RETAIL CONVERSIONS

5.2.171Pendle Borough Council has a clear history of refusing change-of-use applications where residential dwellings are proposed to be converted to retail or commercial use in unsuitable locations. For example, applications at 174 Railway Street, Nelson (Ref. 19/0446/FUL, later re-submitted as 20/0572/FUL) sought to change a dwelling (Use Class C3) to retail (Use Class A1/E); the Council refused the proposal, noting conflict with town centre and retail policies and harm to the vitality and viability of Nelson Town Centre. Similarly, at 55 Newport Street, Nelson (Ref. 20/0682/FUL, later re-submission with retail impact assessment), officers identified that change of use from a dwelling to a shop in an out-of-centre residential street conflicted with the retail hierarchy and local plan policies.

5.2.172 These examples demonstrate that Pendle has previously rejected residential-to-commercial/pharmacy-type proposals where planning policy, location, and amenity considerations were not satisfied. Approving a change of use from an occupied dwelling to a DSP at 12 Commercial Street would therefore run against local planning practice and established precedent in the borough.

5.2.173 Harrogate (Clinical Services Yorkshire Ltd, 16 Claro Court) – NHS Resolution upheld refusal of a DSP application under Regulation 25 where, despite extensive SOPs, the Committee was not satisfied that procedures ensured uninterrupted essential services, safe and effective remote provision, or compliance with key Schedule 4 terms, including cold chain, payment arrangements and exemption handling. The appeal was dismissed because the evidence remained incomplete and ambiguous.

5.2.174 Rowley Regis / Black Country ICB (Goodcure Ltd) – NHS Resolution refused a DSP application where the procedures relied on a "local" delivery driver for controlled drugs and failed to demonstrate how essential services would in practice be provided nationwide, safely, and without face-to-face contact. The Committee found Regulation 25(2)(b)(i)–(ii) not met and refused the application.

5.2.175 National provider Pharmacy2U – An application by Pharmacy2U for a new large-scale dispensing/DSP site was refused after NHS England and the appeal body concluded that its proposals (including appliance and fittings provision) did not meet the regulatory requirements. This shows that even established DSP operators are refused where their evidence and model do not fully satisfy the Regulations.

5.2.176 Medis Pharma Ltd v NHS Resolution – In 2025 the High Court upheld NHS Resolution's refusal of a DSP application, confirming that the Appeals Committee is entitled to expect a complete, coherent, and fully evidenced case at the time of determination, and is not obliged to accept a piecemeal or "iterative" approach where key information and systems are missing or left to be developed later.

5.2.177 These decisions, taken together, demonstrate a clear national pattern: DSP applications are being refused across England where applicants rely on generic SOPs, incomplete information, weak delivery/cold-chain arrangements, or models that blur DSP rules on non-face-to-face provision or true nationwide reach. The Applicant's proposal at 12 Commercial Street falls squarely into this high-risk category and should be treated in the same way – refused.

5.2.1788. Comparative Strength of Brierfield Late Night Pharmacy

5.2.179 This section establishes, in clear and decisive terms, why Brierfield Late Night Pharmacy stands as the credible, experienced, safe, and fully compliant operator in this case. Without relying on awards or external achievements, this section focuses strictly on professional competence,

operational readiness, and regulatory alignment — the areas NHS Resolution must consider under Regulation 25.

5.2.180A. ESTABLISHED NHS CONTRACTOR WITH LONG-TERM SERVICE DELIVERY

5.2.181Brierfield Late Night Pharmacy has operated NHS pharmaceutical services for many years, demonstrating:

5.2.181.1continuous service provision,

5.2.181.2full compliance with NHS contractual requirements,

5.2.181.3consistent engagement with governance,

5.2.181.4a proven ability to deliver safe, effective, uninterrupted care.

5.2.182The Applicant has no operational history and no demonstrated service provision capability.

5.2.183B. PROVEN GOVERNANCE, SAFETY & COMPLIANCE SYSTEMS

5.2.184Your pharmacy already maintains:

5.2.184.1full governance frameworks,

5.2.184.2RP oversight systems,

5.2.184.3clinical SOPs linked to real premises,

5.2.184.4IG compliance procedures,

5.2.184.5risk assessments,

5.2.184.6staff training structures,

5.2.184.7incident reporting and audit cycles,

5.2.184.8business continuity systems.

5.2.185The Applicant has none of these and has provided no evidence of any governance structure.

5.2.186C. FULLY COMPLIANT, LAW-FULLY OPERATING PREMISES

5.2.187Your premises:

5.2.187.1have lawful commercial use,

5.2.187.2have full GPhC registration,

5.2.187.3meet structural and safety standards,

5.2.187.4include secure storage and CD compliance,

5.2.187.5allow safe, effective workflow,

5.2.187.6maintain secure physical protection measures.

5.2.188The Applicant's premises cannot meet even the minimum GPhC requirements.

5.2.189D. ESTABLISHED CAPACITY FOR REMOTE & NATIONAL SERVICE DELIVERY

5.2.190You already operate:

5.2.190.1remote clinical consultations,

5.2.190.2national medicine delivery infrastructure,

5.2.190.3systems ensuring uninterrupted essential service provision,

5.2.190.4cold-chain capability with proper monitoring,

5.2.190.5secure, audited processes for storage and dispatch.

5.2.191The Applicant has no national systems, no remote consultation tools, and no operational model.

5.2.192E. TRAINED WORKFORCE & PROPER PROFESSIONAL OVERSIGHT

5.2.193Your pharmacy employs:

5.2.193.1trained pharmacy staff,

5.2.193.2defined responsibilities,

5.2.193.3competency-assured roles,

5.2.193.4a clear governance chain,

5.2.193.5processes ensuring safe RP cover.

5.2.194The Applicant has no staff, no training plans, and no demonstrated competence in managing healthcare roles.

5.2.195F. RELIABLE, TRUSTWORTHY EVIDENCE BASE — NHS RESOLUTION CAN RELY ON YOUR SUBMISSION

5.2.196Your evidence is:

5.2.196.1factual,

5.2.196.2photographic,

5.2.196.3structural,

5.2.196.4governance-linked,

5.2.196.5operationally grounded.

5.2.197The Applicant's evidence is:

5.2.197.1theoretical,

5.2.197.2generic,

5.2.197.3inconsistent,

5.2.197.4incomplete,

5.2.197.5unsupported.

5.2.198G. CONCLUSION OF COMPARATIVE ANALYSIS

5.2.199The contrast is absolute and decisive:

5.2.199.1You are an established, compliant, fully operational NHS pharmacy.

5.2.199.2The Applicant is an inexperienced, unproven, unprepared entity with no operational capacity.

5.2.200NHS Resolution should give decisive weight to the provider with:

5.2.200.1proven capability,

5.2.200.2demonstrated governance,

5.2.200.3safe operational systems,

5.2.200.4lawful, compliant premises,

5.2.200.5and a track record of delivering regulated healthcare safely.

5.2.201This section establishes the Respondent as the only credible and reliable party in this determination.

5.2.2029. Final Conclusion & Request for Determination

5.2.203This final section brings together the entirety of the legal, regulatory, operational, clinical, and governance failures demonstrated throughout this submission. The conclusion is unequivocal: this application is fatally, structurally, and permanently incapable of meeting the statutory requirements for inclusion on the pharmaceutical list.

5.2.204A. THE APPLICATION FAILS EVERY MANDATORY STATUTORY REQUIREMENT

5.2.205 The Applicant fails:

5.2.205.1 Regulation 25(2)(b)(i) – safe and effective essential services,

5.2.205.2 Regulation 25(2)(b)(ii) – uninterrupted provision,

5.2.205.3 Regulation 25(2)(b)(iii) – non-face-to-face delivery,

5.2.205.4 Regulation 25(2)(b)(iv) – evidence of procedures, governance, systems, and premises.

5.2.206 Failure of ANY limb is fatal. The Applicant fails ALL FOUR.

5.2.207 B. PREMISES ARE UNLAWFUL, UNSAFE, UNREGISTERABLE

5.2.208 The premises:

5.2.208.1 are residential,

5.2.208.2 have tenants,

5.2.208.3 have no planning,

5.2.208.4 cannot gain planning,

5.2.208.5 cannot meet GPhC premises standards,

5.2.208.6 cannot meet safety or disabled access requirements.

5.2.209 This alone renders the application unapprovable.

5.2.210 C. APPLICANT HAS NO GOVERNANCE, NO EXPERIENCE, NO CAPABILITY

5.2.211 The Applicant:

5.2.211.1 is 19,

5.2.211.2 has no NHS experience,

5.2.211.3 has no DSP experience,

5.2.211.4 has no governance systems,

5.2.211.5 has no clinical infrastructure,

5.2.211.6 has never operationalised a pharmacy,

5.2.211.7 failed to open their previous DSP.

5.2.212 This is not inexperience; it is total incapacity.

5.2.213D. EVIDENCE FROM ICB, LPC, CPL AND RESPONDENT REMAINS UNCHALLENGED

5.2.214Not one objection from any statutory or professional body has been rebutted. Not one piece of evidence has been contradicted. The record is entirely one-sided.

5.2.215E. THE APPLICATION REPRESENTS DSP MISUSE AND A POLICY THREAT

5.2.216It fits the exact misuse model identified in the 2024 DSP Pause:

5.2.216.1unsafe operators,

5.2.216.2local targeting,

5.2.216.3speculative applications,

5.2.216.4no national capability

5.2.216.5no readiness.

5.2.217Approving this DSP would contradict national policy and undermine DSP regulation nationally.

5.2.218F. NHS RESOLUTION MUST REFUSE THE APPLICATION

5.2.219Based on:

5.2.219.1statutory failure,

5.2.219.2legal impossibility,

5.2.219.3planning illegality,

5.2.219.4governance absence,

5.2.219.5premises unsuitability,

5.2.219.6national policy considerations,

5.2.219.7risk to public safety,

5.2.219.8total lack of capability,

5.2.219.9the Applicant’s credibility collapse.

5.2.220There is only one possible lawful outcome.

5.2.221CONCLUSION:

5.2.222 The DSP application for 12 Commercial Street MUST BE REFUSED IN FULL, WITHOUT CONDITIONS, WITHOUT QUALIFICATION, AND WITHOUT POSSIBILITY OF DEFERRAL OR RECONSIDERATION.

5.2.223 This application is unsafe, unlawful, unready, unimplementable, and contrary to national DSP policy. It cannot be approved under any interpretation of the Regulations.

5.2.224 We respectfully request NHS Resolution to uphold the ICB's refusal in its entirety."

5.2.225 [Supporting documents were attached including 5 screenshots of searches on Pendle Borough Council website, plus a photograph and a video of the proposed premises]

6 Summary of Observations

This is summary of observations received.

6.1 Rushport Advisory, on behalf of the Applicant

6.1.1 "Thank you for your letter of 17 December 2025. I act for Kim Pharma Limited and have been instructed by my client to submit this response to the comments on my client's appeal from Brierfield Pharmacy.

6.1.2 Whilst Brierfield Pharmacy continues to raise matters that are either not relevant to the legal test or that mis-state the Regulatory framework, they raise a number of issues that we wish to comment on for completeness.

6.1.3 It is noted that in various places within the 23 page letter Brierfield Pharmacy attributes quotes to Rushport. Despite putting words within quotation marks, none of these are in fact quotes, nor are they "repeatedly" stated (see page 6). On pages 7 to 9 Brierfield Pharmacy provides specific quotes that it attributes to our letter of 17 August 2025 that was submitted in response to initial objections received. None of these are in fact quotes. Some of the supposed quotes are not even an attempt to summarise what might have been written and are entirely made up.

6.1.4 Brierfield Pharmacy states that the Applicant is 19 years old with no pharmacy experience. It is assumed that this is a reference to [Mr AG] who is a director of Kim Pharma Ltd. As a non-pharmacist, my client has properly identified their superintendent pharmacist, [Mr A] as the person who will be responsible for the operations of the pharmacy. [Mr A] is a GPhC registered pharmacist and is the person that approved the SOPs that have been provided.

6.1.5 Brierfield Pharmacy makes a number of references to planning permission. As the Committee is aware, planning permission is a matter for the local authority. If the local authority is not satisfied that the premises can be used as a pharmacy then they will not approve planning permission for the premises and the pharmacy cannot trade.

6.1.6 In a similar manner it is the GPhC that is responsible for regulating both pharmacists and pharmacy premises. From experience we are aware that the GPhC is particularly strict when considering any application for a premises that has the appearance of being residential. The GPhC must be fully satisfied on a wide range of matters, from security to operational capability. The GPhC also reviews the website content for all new proposed distance selling pharmacies. No GPhC approval will be given if the premises and operational capabilities are not clearly demonstrated and without GPhC premises approval a pharmacy cannot open.

6.1.7 As the Committee may already be aware, the GPhC used to require evidence of planning approval prior to registering any new pharmacy premises. This requirement caused significant difficulties for the GPhC as some premises did not require specific consent or were approved under different use classes. The requirement was removed some years ago as the GPhC realised that planning was a specialist area that they lacked the required expertise to properly consider and should remain a matter for the local authority.

6.1.8 Brierfield Pharmacy has mixed up the roles and responsibilities of various statutory and local government bodies. In respect of this appeal, and as the Committee is aware, the regulatory test is a forward looking one and requiring the decision maker to be "*satisfied that the pharmacy procedures for the pharmacy premises are likely to secure…"*

6.1.9 It would be quite wrong to try to predict a future breach of any regulation or Terms of Service based on comments from another pharmacy contractor. Any future action would be a matter for contract monitoring by the ICB.

6.1.10 We look forward to hearing from you in due course."

7 Unsolicited comments

7.1 Community Pharmacy Lancashire and South Cumbria

7.1.1 "On behalf of Community Pharmacy Lancashire and South Cumbria I enclose a copy of our original letter arguing against the granting of this contract and politely ask that it be considered as part of the appeal."

Letter to the Commissioner dated 12 July 2025

7.1.2 "Thank you for informing Community Pharmacy Lancashire and South Cumbria (CPLSC) the name adopted by Lancashire and South Cumbria Local Pharmaceutical Committee, of the above application.

7.1.3 We note that this is a Distance Selling Application, and we would be willing to attend an oral hearing if it were to be deemed necessary.

7.1.4 Community Pharmacy Lancashire and South Cumbria have had the opportunity to consider the application and with input from the whole committee CPLSC would like to make the following comments;

7.1.5 ***The 2023 CCA Report on the Impact of "pseudo" distance selling pharmacies***

7.1.6 ***Concluded with evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk.***

7.1.7 **"Failure to regulate rogue businesses is leading to pharmacy closures."**

7.1.8 **Public data shows that there were 372 active DSP Contracts in England at the end of 2022. The prescriptions by each were analysed to determine which GP Surgery prescribed them.**

7.1.9 **268 (72%) are not following their NHS DSP contractual requirements. More than 50% of their prescriptions come from GP's in a single postcode area that is located within 10 miles of the pharmacy.**

7.1.10 **28 (72%) are not following their NHS DSP requirements. More than 50% of their prescriptions come from GP's in a single postcode area. However more than 50% of their prescriptions come from more than 10 miles from the pharmacy.**

7.1.11 **15 (4%) receive up to 50% of their prescriptions come from GP's in a single postcode area. However fewer than 50% of their prescriptions come from more than 10 miles from the pharmacy.**

7.1.12 **Only 63 (16%) receive prescriptions from across the country and provide the service expected of DSP's**

7.1.13 Imran Ayaaz is named as the Pharmacy Superintendant [sic] but today 12/07/2025 he is not named as a Superintendant [sic] on the GPhC register.

7.1.14 There are three other pharmacies within 1 mile of the pharmacy.

7.1.15 We note the provision of a wholly generic standard set of SOP's from Rushport.

7.1.16 We note the minimum 40 hours of pharmacy coverage (wholly during the daytime when other pharmacies are open) and ask what benefit that brings to the local or national population.

7.1.17 We note the absence of a floorplan and would ask that consideration to adequate security is looked at, an issue that has been a problem in pharmacies previously in Lancashire and South Cumbria.

7.1.18 Additionally having looked at the proposed location of the pharmacy despite the name "Commercial Street" it appears to be situated in the middle of a block of terraced houses in a residential area of Brierfield!

I'm not a planning expert but I would expect some change of use would be required to turn a house into a DSP?

7.1.19 There is no lack of DSP pharmacies already operating in Lancashire and South Cumbria.

7.1.20 We would ask that it is noted, that this application will in no way cause any loss of pharmaceutical cover.

7.1.21 In summary, there is evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk and we urge the ICS to ensure that if this pharmacy is approved that it is audited to ensure its does not operate in breach of its contract."

8 Consideration

8.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.

8.2 It also had before it the responses to NHS Resolution's own statutory consultations.

8.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

8.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

8.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") at or from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

8.6 The Committee noted that at section 5 of the application form, the Applicant had stated "*Not applicable as no other pharmacy in same or adjacent premises*". The Commissioner had determined that Regulation 31 does not apply, stating "*The Group noted that Regulation 31 does not apply, as the applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide*." The Committee noted there was no dispute on the matter from other parties.

8.7 Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

8.8 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

"(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

(2) NHS England must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

(ii) the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

8.9 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

8.10 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

8.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*". The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

8.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

8.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.

8.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

8.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the updated SOPs which the Applicant has prepared or commissioned.

8.16 The Committee noted Brierfield Late Night Pharmacy's comments regarding the Committee's past approach. In this regard, it is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

8.17 The Committee first considered how the Applicant would provide essential services without interruption and noted the following information in the Applicant's SOPs:

8.18 SOP 1: "Introduction and Background to SOPs"

8.18.1 "*1.3 Overriding Provisions Applicable to All SOPs*

The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

8.19 SOP 34: "The Responsible Pharmacist"

8.19.1 "*34.9 Absence of the RP*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require <u>a pharmacist</u> to be present so that services are not interrupted. [Applicant's emphasis]

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

8.20 With regard to services being available to persons anywhere in England and mindful of Brierfield Late Night Pharmacy's claim that if the application is granted, the Applicant will target the local population, the Committee noted the following information in the Applicant's SOPs:

8.21 SOP 1: "Introduction and Background to SOPs"

8.21.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide… to persons anywhere in England who request those services."

8.22 SOP 3: "Procedures for NHS Pharmaceutical Services"

8.22.1 "*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet.*"

8.23 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted that in its decision report the Commissioner had concluded *"…from the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations, particularly in regards to face-to-face provision.*" The Committee also noted the comment from Brierfield Late Night Pharmacy that "*The Applicant provided no mechanisms, layout, staffing flows, or procedures to ensure no facetoface activity. A residential, tenant occupied property cannot operate without contact.*"

8.24 The Committee noted the following information in the Applicant's SOPs:

8.25 SOP 1: "Introduction and Background to SOPs"

8.25.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide;

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises…

… All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."

8.26 SOP 3: "Procedures for NHS Pharmaceutical Services" 6.26.1

8.26.1 "*3.1 Communication Channels*

All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."

8.26.2 "*3.2 Request for face-to-face service provision*

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Applicant's emphasis]

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

8.27 Further, the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

8.28 In its application the Applicant stated that it intended to provide "*NMS (remotely with consent where required)*". The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call.*"

8.29 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

8.30 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and pharmaceutical services would be provided without face to face contact. The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

8.31 The Committee considered pharmaceutical services including each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

Dispensing of drugs and appliances

8.32 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

8.33 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

8.33.1 *"…Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

8.34 SOP 6 'Online Order Receipt & Exemption Checking' states:

8.34.1 "*6.2 Scope*

All online services including the following:

…Requests to collect and dispense NHS Prescriptions."

8.34.2 "*6.7 Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post…"

8.35 SOP 20 'Order Delivery' states:

8.35.1 "*20.6 Choice of Delivery Method*

For items <u>other than</u> cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below). [Applicant's emphasis]."

8.36 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

8.37 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

Urgent supply without a prescription

8.38 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

8.39 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' (SOP 17) which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

8.40 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

8.41 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.

8.42 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking states:

8.42.1 "*6.8 Exempt NHS Prescriptions*

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

8.43 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

8.44 The Committee considered whether the Applicant had explained how charges will be paid.

8.45 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' states:

8.45.1 "*6.11 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

8.46 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

8.47 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met). The Committee noted that the Commissioner had refused the application on 'cold chain' but had not articulated why.

8.48 The Committee noted SOP 20 'Order Delivery' states:

8.48.1 "*20.10 Transfer to the Delivery Driver*

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Ensure that any special instructions for the delivery are included with the packaging.

Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.

Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

Ensure the delivery driver is notified of any messages for the patient or representative.

Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended."

8.48.2 "*20.11 Delivery of prescription to patient or representative address*

Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

8.48.3 "*20.12 Successful delivery*

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

8.48.4 "*20.13 Unsuccessful Delivery*

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

8.48.5 "*20.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

Follow preparation for delivery process. The pharmacist must contact any patients for whom there are relevant messages or counselling required.

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

All deliveries will require a signature from the patient to confirm receipt of their prescription."

8.48.6 "*20.16 Cold chain delivery via courier*

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

…Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge

line sticker. Accompanying items must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.

The cold chain item must be kept in the fridge until the courier arrives to accept the delivery.

Confirm with the courier that the delivery will be maintained at the booked temperature range.

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number."

8.48.7 "*20.17 Unsuccessful cold chain delivery via courier*

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery."

8.48.8 "*20.18 Breach of Integrity of Cold Chain*

The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.

The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return

of the items that have failed to be delivered to the pharmacy by the courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

8.49 SOP 24 'Controlled Drugs: Delivery' states:

8.49.1 "*24.5 Delivery of Schedule 2 & 3 CDs*

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

8.49.2 "*24.6 Successful Schedule 2 & 3 Delivery*

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."

8.49.3 "*24.7 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."

8.49.4 "*24.8 Unsuccessful Schedule 2 & 3 Delivery via courier*

Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

8.49.5 "*24.9 Note re Use of Couriers for Controlled Drugs Deliveries*

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

8.50 The Committee noted Brierfield Late Night Pharmacy's view that the Applicant has "*no cold-chain capability*". Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

8.51 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/ measuring, a registered pharmacist measures/fits them.

8.52 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated *"Drug Tariff part IX* *EXCEPT items that require measuring or fitting".*

8.53 The Committee noted the Applicant's SOPs state:

8.54 SOP 10 'Pharmaceutical & Legal Assessment':

8.54.1 "*10.9 Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)"

8.55 SOP 27 'Support for Self-Care, Signposting and Health Promotion':

8.55.1 "*27.14 Items Requiring Measuring and Fitting*

Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)"

8.56 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

8.57 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items.

8.58 The Committee noted that SOP 19 'Bagging-Up' states:

8.58.1 "*19.7 Choice of Packaging*

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and

"FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used." [Applicant's emphasis]

8.59 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

8.60 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment.

8.61 The Committee noted SOP 35 'Repeat Dispensing' states:

8.61.1 "*35.10 Prescription reception*

The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

8.61.2 "*35.11 Pharmaceutical & Legal Assessment*

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP.

The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

8.62 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

Further activities to be carried out in connection with the provision of dispensing services

8.63 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

8.64 The Committee noted SOP 35 'Repeat Dispensing' states:

8.64.1 "*35.10 Prescription Reception*

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them."

8.64.2 "35.11 *Pharmaceutical & Legal Assessment*

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

…Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."

8.65 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

8.66 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

8.67 The Committee noted SOP 25 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

8.67.1 "*25.5 Patient Returned Medication*

This service is available to <u>all</u> patients living in England.

Patients or their representatives <u>may not</u> return and medicines directly to the pharmacy and must follow the procedures set out in this SOP. [Applicant's emphasis]

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return

by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

8.67.2 "*25.7 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

8.67.3 "*25.8 Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date."

8.68 SOP 26 'The Safe and Effective Receipt and Disposal of Medicines' states:

8.68.1 "*26.6 Process for Patients to Return Medication*

Patient Returned Medication

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient"

8.68.2 "*26.7 Process for accepting patient returns by the Driver*

Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags.

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times."

8.68.3 "*26.9 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

8.68.4 "*26.10 Disposal of returned medicines*

Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect."

8.69 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

8.70 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

8.71 The Committee noted SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.71.1 "*28.3 Identification of patients for promotion of Healthy Lifestyles*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle

questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

8.71.2 "*28.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

…We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times."

8.72 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

8.73 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

8.74 The Committee noted SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.74.1 "*28.6 Long Term Conditions*

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

8.74.2 "*28.7 Identification of patients for Support with Long Term Conditions*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."

8.75 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

8.76 The Committee considered whether the Applicant had explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the Commissioner.

8.77 The Committee noted SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.77.1 "*28.4 Health Campaigns & Community Engagement Exercise*

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."

8.78 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

8.79 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

8.80 The Committee noted SOP 27 'Support for Self-Care, Signposting and Health Promotion' states:

8.80.1 "*27.10 Other Provider Organisations and Support Details*

Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should [sic] *be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email.*"

8.80.2 "*27.12 Signposting*

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

8.80.3 "*27.13 Patient Identification*

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

requires advice, treatment or support that we cannot provide; but

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."

8.81 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

8.82 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

8.83 The Committee noted SOP 27 'Support for Self-Care, Signposting and Health Promotion' states:

8.83.1 "*27.8 Patient Identification*

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

8.83.2 "*27.9 Service outline*

Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service.

…The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

8.84 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Discharge medicines service

8.85 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

8.86 Further, the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.

8.87 The Committee noted SOP 29 'Discharge Medicines Service ("DMS")' states:

8.87.1 "*29.3 Process*

Every day the RP must check the pharmacy's NHS.net Connect system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen".

8.87.2 "*29.4 Consent*

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

8.87.3 "*29.5 DMS Stages*

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

8.87.4 "*29.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)*

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

8.87.5 "*29.7 Considering the appropriateness of any medication changes prior to discharge*

DMS requests will not necessarily all be in the same form.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE"

8.87.6 "*29.8 DMS Stage 2*

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate

changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

8.87.7 "*29.9 DMS Stage 3*

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their

associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

8.88 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

8.89 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

8.90 The Committee noted that SOP 27 'Support for Self-Care, Signposting and Health Promotion' states:

8.90.1 "*27.11 Health promotion zone on our website*

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

8.91 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Other considerations

8.92 The Committee noted Brierfield Late Night Pharmacy's comment that "*The Applicant is a 19 year old with no pharmacy background, no superintendent pharmacist, no governance systems, no training, no staff, no planning, and no operational capacity*" and reference to the Applicant's previous applications. Notwithstanding the fact that the age and experience of any applicant are not a relevant consideration under the test, the Committee noted Rushport had stated "*As a non-pharmacist, my client has properly identified their superintendent pharmacist, Mr [A] as the person who will be responsible for the operations of the pharmacy. Mr [A] is a GPhC registered pharmacist and is the person that approved the SOPs that have been provided.*" The Committee noted that the Applicant had named a Superintendent Pharmacist on the application form and the Commissioner had confirmed that fitness to practise checks had been carried out and were found satisfactory. On the matter of the Applicant's past history, the Committee considered that it would not be fair to treat the Applicant differently to those applicants who had operated distance selling pharmacies. The Committee next considered Brierfield Late Night Pharmacy's comment that the proposed premises are "*…a fully occupied residential dwelling—remain untouched, unconverted, unlawful for pharmacy use, and structurally incapable of ever meeting GPhC or DSP contractual requirements.*" There are also comments regarding premises security and readiness. In response, Rushport state "*…planning permission is a matter for the local authority. If the local authority is not satisfied that the premises can be used as a pharmacy then they will not approve planning permission for the premises and the pharmacy cannot trade.*" Further, Rushport state "*…the GPhC is particularly strict when considering any application for a premises that has the appearance of being residential. The GPhC must be fully satisfied on a wide range of matters, from security to operational capability. The GPhC also reviews the website content for all new proposed distance selling pharmacies. No GPhC approval will be given if the premises and operational capabilities are not clearly demonstrated and without GPhC premises approval a pharmacy cannot open.*" The Applicant has also commented that "*No change planning applications have been made…*". The Committee noted that, if the application were granted, the Applicant would have a period of 12 months within which to submit a notice if commencement, subject to extension if agreed by the Commissioner. The Committee was also mindful that the pharmacy would not be able to open if it did not satisfy the relevant requirements for both planning permission and GPhC premises approval.

Summary

8.93 On the information before it, the Committee could be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

8.94 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:

8.94.1 confirm the Commissioner's decision;

8.94.2 quash the Commissioner's decision and redetermine the application;

8.94.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

8.95 Given that the Committee had reached a different decision to the Commissioner, it determined that the decision of the Commissioner must be quashed.

8.96 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

8.97 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

8.98 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

9 Decision

9.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

9.2 The Committee:

9.2.1 quashes the decision of the Commissioner; and

9.2.2 redetermines the application as follows -

9.2.2.1 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

9.2.2.2 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;

9.2.2.3 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;

9.2.2.4 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

9.2.2.5 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

9.2.3 The application is granted.

Case Manager
Primary Care Appeals